**STATE OF MISSOURI**
**MISSOURI BOARD OF PHARMACY**

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| IN RE: | ) | |
| | ) | |
| REHOBOTH PHARMACY, LLC | ) | |
| 9944 W. Florissant | ) | Complaint No. 2017-003495 |
| St. Louis MO 63136 | ) | |
| Permit No. 2007000836 | ) | |

**SETTLEMENT AGREEMENT BETWEEN MISSOURI BOARD OF PHARMACY AND REHOBOTH PHARMACY, LLC**

COME NOW Rehoboth Pharmacy, LLC ("Respondent" or the "Pharmacy") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and

voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 2007000836, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo

## JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo (2016)[1], for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Rehoboth Pharmacy, LLC, 9944 W. Florissant, St. Louis, MO 63136 is permitted by the Board under permit number 2007000836. Respondent's permit was at all times relevant herein current and active.

3. At all times relevant herein, Idowa A. Ajibola was employed as the pharmacist in charge ("PIC") of the Pharmacy.

[1] All statutory references are to the Revised Statutes of Missouri 2000, as amended, unless otherwise stated.

**March 20, 2015 Inspection**

4. On or about March 20, 2015, Board Inspector Bennie Dean visited the Pharmacy to conduct a routine inspection. An Observation Report was provided to the Pharmacy detailing the violations observed by Inspector Dean on that date.

Failure to Maintain Pharmacy in Sanitary Condition

5. During her March 20, 2015, inspection of the Pharmacy, Inspector Dean inspected the sanitary conditions of the Pharmacy.

6. She observed that the tubing on the water dispenser was caked with dried medication and that the prescription area was cluttered and not clean and had no working counter space.

7. She also observed sawdust, boxes and totes on the floor and dried paint on the counter.

8. Missouri law requires:

> (F) All pharmacies shall be maintained in a clean and sanitary condition at all times. Any procedures used in the dispensing, compounding and admixture of drugs or drug-related devices must be completed under clean and, when recommended, aseptic conditions.
> 1. Appropriate sewage disposal and a hot and cold water supply within the pharmacy must be available.
> 2. Appropriate housekeeping and sanitation of all areas where drugs are stored or dispensed must be maintained. 20 CSR § 2220-2.010(1)(F).

9. By having dried medication on the tubing of the water dispenser; a cluttered prescription area with no working counter space; and sawdust, boxes and totes on the floor and dried pain on the counter the Pharmacy was not in a clean or sanitary condition in violation of 20 CSR § 2220-2.010(1)(F).

Dispensing Errors

10. During her March 20, 2015, inspection of the Pharmacy, Inspector Dean also reviewed the Pharmacy's dispensing and prescriptions records.

11. She noted dispensing errors for prescription nos. 23508 and 23520.

12. The Pharmacy's dispensing errors constitute a violation of professional trust and confidence under § 338.055.2(13), RSMo.

Failure to notify Board of remodeling plans

13. During her March 20, 2015, inspection of the Pharmacy, Inspector Dean also observed that the Pharmacy was being remodeled.

14. 20 CSR § 2220-2.020(4)(A) provides:

> (A) Remodeling of a licensed pharmacy within an existing structure shall be deemed to have occurred when any change in the storage conditions of the Schedule II controlled substances is made or new connections to water/sewer resources are made or any changes in the overall physical security of drugs stored in the pharmacy as defined in 20 CSR 2220-2.010(1)(H) are made. Remodeling as defined within this section will not require the initiation of any change of location procedures. Satisfactory evidence of plans for any remodeling of a pharmacy must be provided to the board office thirty (30) days in advance of commencing such changes along with an affidavit showing any changes to the pharmacy physical plant and the projected completion date for any remodeling.

15. The Pharmacy violated 20 CSR § 2220-2.020(4)(A) by failing to give the Board its remodeling plans 30 days in advance of the remodeling commencement date along with an affidavit showing any changes to the Pharmacy physical plant and the projected completion date for the remodeling.

Return to stock violation

16. During her March 20, 2015, inspection of the Pharmacy, Inspector Dean also reviewed the Pharmacy's prescriptions that were returned to stock.

17. She observed that two prescriptions that had been returned to stock – prescription nos. 711628 filled July 5, 2011 and 7116485 filled January 11, 2013 – had expiration dates greater than 12 months from the dispensing date.

18. 20 CSR § 2220-3.040(3) states:

> (3) Pharmacists and pharmacies may return to stock prescriptions that have not been received by the patient and shall delete the dispensing from the pharmacy's records and reverse the claim with the third party payor, if applicable. In order for a product to be returned to stock, it must have been stored at all times at the manufacturer's labeled storage requirements. The drug must be maintained in the patient container with the dispensing date, prescription number, and name of drug visible. The expiration date of the drug shall become the lesser of one (1) year from the dispensing date on the label or the manufacturer's original expiration date, if known. 20 CSR § 2220-3.040(3).

19. The Pharmacy violated 20 CSR § 2220-3.040(3) by maintaining returned to stock items with expiration dates greater than 12 months from the dispensing dates.

Outdated Drugs in Active Inventory and Misbranding

20. During her March 20, 2015, inspection of the Pharmacy, Inspector Dean also reviewed the Pharmacy's inventory.

21. She observed outdated drugs in the Pharmacy's active inventory.

22. Missouri law states:

> (6) Drugs and devices that are maintained as part of the pharmacy inventory or are being processed for dispensing or other distribution purposes must be physically separated at all times from articles, supplies or other drugs that are for employee personal use or that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances. Areas used for this type of drug storage must be clearly identified. 20 CSR § 2220-2.010(6).

23. By maintaining expired drugs in its active drug inventory, the Pharmacy was in violation of 20 CSR § 2220-2.010(6).

24. Inspector Dean also observed a manufacturer's stock bottle overfilled with 120 tablets at the Pharmacy.

25. Overfilling stock bottles constitutes misbranding and violates Missouri law, to-wit:

> The following acts and the causing thereof within the state of Missouri are hereby prohibited:
>
> > (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
> >
> > (2) the adulteration or misbranding of any food, drug, device, or cosmetic; §196.015(1)-(2), RSMo.

26. Misbranding of a drug under Missouri law is defined in § 196.100.1, RSMo, which states in pertinent part:

> 1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.

27. Federal law also prohibits misbranding, to-wit:

> (a) The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.
>
> (b) The adulteration or misbranding of any . . . drug . . . in interstate commerce. 21 U.S.C. § 331(a)-(b).

28. A legend drug is misbranded under 21 U.S.C. §352(a)(1) of the Federal Food, Drug and Cosmetic Act, as amended, "[i]f its labeling is false or misleading in any particular."

29. By overfilling stock bottles, the Pharmacy misbranded a legend drug product because the labels on the stock bottles were false and misleading in violation of §196.015, RSMo, §196.100, RSMo, 21 U.S.C. §352(a)(1), 21 U.S.C. §331(a)-(b).

**March 2015 Compliance Notice**

30. Upon completion of her March 20, 2015, inspection, Inspector Dean issued a Compliance Notice to the Pharmacy

31. The 2015 Compliance Notice requested a written response from the Pharmacy no later than April 1, 2015.

32. On or about April 13, 2015, the Board received a written response to the March 2015 Compliance Notice.

33. The written response was signed by Mr. Ajibola as PIC.

34. Regarding the Pharmacy's failure to advise the Board of its remodeling plans, the Pharmacy responded that it had been broken into and looted twice as a result of the events in Ferguson and that Mr. Ajibola, his family and his staff were exposed to a dangerous environment. The response also stated that the Board and the BNDD were called to report the situation.

35. Regarding the Pharmacy's outdated drugs in active inventory, the Pharmacy responded that most of the outdated drugs were March 2015 waiting to be pulled and a few missed ones from the last check.

36. Regarding the misbranding by maintaining overfilled stock bottles, the Pharmacy responded that 20 tablets were added to the original bottle of 100 and stated "that will be corrected."

## Corrective Action Plan

37. The Board sent correspondence dated June 1, 2015 to Mr. Ajibola as PIC of the Pharmacy requesting that the Pharmacy submit a Corrective Action Plan identifying how the Pharmacy would address the compliance issues noted in the March 20, 2015 Observation Report and Compliance Notice.

38. On or about June 30, 2015, the Board received a Corrective Action Plan from the Pharmacy.

39. With regard to the unsanitary/unclean conditions, the Pharmacy stated it was cleaned and was made orderly and that it would conduct a weekly/monthly inspection of working areas and a Pharmacy self-assessment.

40. With regard to insufficient work space, the Pharmacy stated "counters now clean for work spaces" and that it would make sure the counter working area is free and paper clutter.

41. With regard to dispensing errors, the Pharmacy stated "error-proof system re-visited, intensified protocol to minimize prescription errors."

42. With regard to outdated drugs in inventory, the Pharmacy stated "all outdated drugs removed from active inventory" and "sticker system employed."

## July 7 and July 30, 2015 Remodeling Inspections

43. On or about July 7 and July 30, 2015, Board Inspector Bennie Dean visited the Pharmacy to conduct remodel inspections.

44. During her July 7, 2015, remodel inspection, Inspector Dean noticed that the roof was leaking and that there were no walls to the roof.

45. During her July 30, 2015 remodel inspection, Inspector Dean noticed that walls to the roof were not completed.

46. The Pharmacy was not in a clean or sanitary condition due to the leaking roof and the lack of walls in violation of 20 CSR § 2220-2.010(1)(F).

**March 28, 2016 Inspection**

47. On or about March 28, 2016, Inspector Dean returned to the Pharmacy to conduct a routine inspection. An Observation Report was provided to the Pharmacy detailing the violations observed by Inspector Dean on that date.

Failure to Maintain Pharmacy in Sanitary Condition

48. During her March 28, 2016, inspection of the Pharmacy, Inspector Dean also observed that the prescription area was cluttered.

49. The cluttered state of the prescription area violated 20 CSR § 2220-2.010(1)(F).

50. This was a repeat violation.

Failure to maintain prescription drug delivery policies and procedures

51. During her March 28, 2016, inspection of the Pharmacy, Inspector Dean inspected the Pharmacy's prescription drug delivery policies and procedures.

52. She found that the Pharmacy failed to maintain written prescription drug delivery policies and procedures.

53. 20 CSR 20 § 2220-2.013(1) requires:

> (1) Every pharmacy delivering prescription drugs shall develop and implement written policies and procedures to ensure the safe and appropriate delivery of prescription drugs within the temperature requirements recommended by the manufacturer or the United States Pharmacopeia (USP). Except as otherwise provided herein, prescriptions filled by a Missouri licensed pharmacy may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy.

54. The Pharmacy's failure to develop and implement written policies and procedures regarding the delivery of prescription drugs was in violation of 20 CSR § 2220-2.013(1).

Outdated Drugs in Active Inventory

55. During her March 28, 2016, inspection, Inspector Dean also reviewed the Pharmacy's active inventory.

56. She noted that 20 drugs in the Pharmacy's active inventory had expired in 2016, 12 drugs had expired in 2015, two drugs had expired in 2014, and three drugs had expired in 2012.

57. Maintaining outdated drugs in the Pharmacy's active inventory violated 20 CSR § 2220-2.010(6).

58. This was a repeat violation.

Dispensing Errors

59. During her March 28, 2016, inspection, Inspector Dean also reviewed the Pharmacy's dispensing and prescriptions records.

60. She noted incorrect dispensing directions on the label of prescription no. 304796.

61. The Pharmacy's dispensing error constitutes a violation of professional trust and confidence under § 338.055.2(13), RSMo.

Failure to adequately secure controlled substances

62. During her March 28, 2016, inspection, Inspector Dean also reviewed the Pharmacy's storage of its controlled substances.

63. She observed that Schedule II controlled substances were not stored under lock. The keys were in the lock of the cabinet when she arrived at the Pharmacy.

64. Missouri law more specifically sets forth standards for the storage and holding for sale of controlled substances, to-wit:

(1) Physical Security.
(A) Controlled substances listed in Schedules I and II shall be stored in a securely locked, substantially constructed cabinet.
19 CSR § 30-1.034(1)(A)

65. By having the key in the lock of the cabinet storing Schedule II controlled substances, the Pharmacy was in violation of 19 CSR § 30-1.034(1)(A).

**March 2016 Compliance Notice**

66. Upon completion of her March 28, 2016, inspection, Inspector Dean issued a Compliance Notice to the Pharmacy regarding the Pharmacy's outdated drugs in active inventory.

67. The March 2016 Compliance Notice requested a written response from the Pharmacy no later than April 8, 2015.

68. On or about April 18, 2016, the Board received a written response.

69. The written response was signed by Mr. Ajibola as PIC and stated, "I am going to work more effectively to clear these problems."

**December 13, 2016 Inspection**

70. On or about December 13, 2016, Board Inspectors Joe Dino and Dan Vandersand conducted a routine inspection of the Pharmacy. An Observation Report was provided to the Pharmacy detailing the violations observed by the Inspectors on that date.

Outdated Drugs in Active Inventory

71. During their December 13, 2016, inspection, the Inspectors reviewed the Pharmacy's active inventory.

72. They noted that 21 drugs in the Pharmacy's active inventory had expired.

73. Maintaining outdated drugs in the Pharmacy's active inventory violated 20 CSR § 2220-2.010(6).

74. This was a repeat violation.

Dispensing Errors

75. During their December 13, 2016, inspection, the Inspectors also reviewed the Pharmacy's dispensing and prescriptions records.

76. They noted the following dispensing errors:

A. prescription no. 305223, dispensed on October 12, 2016, was written as butalbital/asa/caffeine/codeine #3 and was dispensed as butalbital/APAP/caffeine/codeine #3;

B. prescription no. 305253 dispensed on November 5, 2016, was written as 1 bid and was dispensed as 1 po tid;

C. prescription no. 305257 dispensed on November 5, 2016, was written as 1-2 tsp qid prn and was dispensed as 1 tsp po qid prn;

D. prescription no. 305265 dispensed on November 10, 2016, was written as butalbital/asa/caffeine/codeine #3 and was dispensed as butalbital/APAP/caffeine/codeine #3; and

E. prescription no. 24451 dispensed on December 1, 2016, was written as 1-2 po q 4 prn p and was dispensed as 1 po q 4 prn p.

77. The Pharmacy's dispensing errors constitute a violation of professional trust and confidence under § 338.055.2(13), RSMo.

78. Quality assurance reports were issued to the Pharmacy for the dispensing errors.

Failure to appropriately electronically record receipts of CSOS orders

79. During their December 13, 2016, inspection, the Inspectors determined that the Pharmacy was not creating records of its receipt of controlled substances from its supplier/s or electronically linking the records to the original order and archiving the records.

80. Specifically, the Pharmacy did not create such records or link the records for Schedule II controlled substance orders received on November 10, 2016, November 14, 2016, November 16, 2016, and November 23, 2016.

81. 21 CFR § 1305.22(g) states that when a purchaser receives a shipment of controlled substances, "the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."

82. By failing to creating records of its receipt of controlled substances from its supplier/s and electronically linking them to the original order and archiving them, the Pharmacy was in violation of 21 CFR § 1305.22(g).

Controlled Substance Inventory Violation

83. During their December 13, 2016, inspection, the Inspectors also reviewed the Pharmacy's annual controlled substance inventory records.

84. They noted that the annual controlled substance inventory was taken July 11-13, 2016.

85. Missouri law states:

> (D) A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken. 19 CSR § 30-1.042(1)(D).

86. The Pharmacy's failure to take its annual controlled substance inventory at the opening or closing of business was in violation of 19 CSR § 30-1.042(1)(D).

Failure to Maintain Pharmacy in Sanitary Condition

87. During their December 13, 2016, inspection, the Inspectors also observed that the pharmacy area was cluttered and had minimal counter space.

88. The cluttered state of the pharmacy area and minimal counter space of the Pharmacy violated 20 CSR § 2220-2.010(1)(F).

89. This was a repeat violation.

**December 2016 Compliance Notice**

90. Upon completion of the December 13, 2016, inspection, Inspectors Dino and Vandersand issued a Compliance Notice to the Pharmacy regarding the Pharmacy's two repeat violations.

91. The December 2016 Compliance Notice requested a written response from the Pharmacy no later than December 23, 2016.

92. On or about December 20, 2016, the Board received a written response to the December 2016 Compliance Notice.

93. The written response was signed by Mr. Ajibola as PIC and stated, with regard to the outdated drugs in active inventory, "I am promising with my personal responsibility" that he would do "monthly checking rather than every other month."

94. With regard to the pharmacy area being cluttered with minimal counter space, Mr. Ajibola responded that, "I am removing all unnecessary boxes, shelves, computers, etc., off the counter, unnecessary chairs, desks and boxes will be removed from pharmacy."

**June 13, 2017 Inspection**

95. On or about June 13, 2017, Inspectors Dean and Vandersand conducted another routine inspection of the Pharmacy. An Observation Report was provided to the Pharmacy detailing the violations observed by the Inspectors on that date.

Temperature exceeded normal range

96. During their June 13, 2017, inspection, the Inspectors observed that the temperature in the Pharmacy was 85.1 degrees.

97. Missouri law requires:

> (G) The temperature of the facility where drugs are stored must be maintained thermostatically within temperature requirements as provided for by the manufacturer or the latest edition of the USP. Adequate refrigeration must be available to insure enough storage space for drugs requiring refrigeration or freezing and under temperatures adequate to maintain the drug products as recommended by the manufacturer, the latest edition of the USP, or both.
>
> 20 CSR § 2220-2.010(1)(G).

98. By maintaining the temperature at 85.1 degrees in June 2017, the Pharmacy violated 20 CSR § 2220-2.010(1)(G).

Outdated Drugs in Active Inventory

99. During their June 13, 2017, inspection, the Inspectors also reviewed the Pharmacy's active inventory.

100. They noted that 30 over-the-counter items had expired.

101. Maintaining outdated drugs in the Pharmacy's active inventory of over-the-counter products violated 20 CSR § 2220-2.010(6).

Controlled substance prescription violations

102. During their June 13, 2017, inspection, the Inspectors also reviewed the Pharmacy's controlled substances prescriptions.

103. They observed that controlled substance prescription no. C-305468 was a facsimile prescription that had been prepopulated by the Pharmacy and that the Pharmacy had not maintained the date or time of the facsimile nor had it maintained the originating fax number for this prescription.

104. Federal law states:

> (f) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.
>
> 21 CFR § 1306.05(f)

105. Dispensing a controlled substance prescription prepopulated by the Pharmacy and not prepared by the practitioner violated 21 CFR § 1306.05(f).

106. Missouri law requires:

> (8) Any pharmacy receiving a controlled substance prescription transmitted by facsimile equipment shall maintain the facsimile copy of the prescription along with the date and time of transmission and the telephone number of the facsimile machine from which it originated, as a part of its original prescription records.
>
> 19 CSR § 30-1.048(8).

107. The Pharmacy's failure to maintain the date and time of faxed prescription no. C-305468 along with the telephone number of the facsimile machine from which it originated violated 19 CSR § 30-1.048(8).

**Follow-up inspections**

108. On July 17, July 25 and August 14, 2017, Inspector Dean went to the Pharmacy to follow-up on the temperature inside the Pharmacy.

109. While she was present on July 17, 2017, the Pharmacy's wall thermostat read 79 degrees and Inspector Dean's calibrated thermometer four-feet from the thermostat read 81.9 degrees.

110. The Pharmacy's thermometer on a shelf above the work area six feet into the Pharmacy read 80 degrees while Inspector Dean's calibrated thermometer six inches from the one on the Pharmacy's shelf read 82.7 degrees.

111. While she was present on July 25, 2017, the Pharmacy's wall thermostat read 77 degrees and Inspector Dean's calibrated thermometer four feet from the thermostat read 80 degrees.

112. Inspector Dean's calibrated thermometer placed in one of the Pharmacy's bays of drugs containing ophthalmic and otic preparations read 82.7 degrees.

113. The manufacturer package statement for the ophthalmic and otic preparations indicated that storage temperatures for the preparations were not to exceed 77 degrees.

114. While Inspector Dean was present on August 14, 2017, the Pharmacy's wall thermostat read 77 degrees and her calibrated thermometer four-feet from the thermostat read 81.8 degrees.

115. The Pharmacy's thermometer on a shelf above the work area six feet into the Pharmacy read 78 degrees while Inspector Dean's calibrated thermometer six inches from the Pharmacy's thermometer on the shelf read 82.7 degrees.

116. In the bay of drugs which contained ophthalmic and otic preparations for which the manufacturer recommended temperatures not to exceed 77 degrees, Inspector Dean's calibrated thermometer read 82.8 degrees.

117. A summary of the temperatures inside the Pharmacy in July and August 2017 are as follows:

| Date | Thermostat on wall | Chair 4 feet from thermostat | Shelf/therm. | In bay of drugs |
|---|---|---|---|---|
| 7/17/17 | 79 degrees | 81.9 degrees | 82.7 degrees | |
| 7/25/17 | 77 degrees | 80.0 degrees | 82.0 degrees | 82 degrees |
| 8/14/17 | 77 degrees | 81.8 degrees | 82.7 degrees | 82.8 degrees |

118. By maintaining the temperature above the manufacturer's recommended temperature for drug products in July and August 2017, the Pharmacy was in violation of 20 CSR § 2220-2.010(1)(G).

**Cause to Discipline**

119. Cause exists for Petitioner to take disciplinary action against Respondent's permit to practice pharmacy for its violation of §338.210.5, which provides:

> 5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

120. Further cause exists for Petitioner to take disciplinary action against Respondent's pharmacy permit pursuant to 20 CSR 2220-2.010(1)(O), which states:

> (O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

121. Respondent's conduct is cause for disciplinary action against its permit to operate a pharmacy under §338.055.2(5), (6), (13), and (15), RSMo, which provides:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
>
> * * *
>
> (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
>
> * * *
>
> (13) Violation of any professional trust or confidence;
>
> * * *
>
> (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

## JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.1, RSMo:

A. Respondent's permit numbered 2000148442 shall be placed on **PROBATION** for a period of **THREE (3) YEARS** ("disciplinary period"). The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

**The following terms apply for the entire disciplinary period.**

1. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.

2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.

4. If, after disciplinary sanctions have been imposed, Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

5. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

6. Respondent shall not serve as an intern training facility for Missouri interns.

7. Respondent shall select an independent pharmacist consultant for the purpose of reviewing and insuring the pharmacy's compliance with all applicable laws and regulations. The consultant shall be a Missouri licensed pharmacist whose license is current and not subject to disciplinary action by the Board. Within thirty (30) days of the beginning of probation Respondent shall submit documentation and credentials of its chosen consultant to the Board office for approval. Within thirty (30) days of the beginning of probation the said consultant shall visit the

pharmacy, evaluate and provide corrective actions to remedy the issues outlined in this agreement/order, conduct a review for compliance with all applicable laws and regulations using the Board's Pharmacy Self-Assessment Form, and submit a written report to the Board office within thirty (30) days of the visit. The consultant's report shall include the suggested corrective actions, a timeline for the pharmacy to complete such corrective actions, items/areas reviewed for compliance with applicable laws and regulations during the visit, any deficiencies noted, and a plan to correct any deficiencies noted. The consultant shall then conduct similar visits and provide ongoing reports to the Board office on a six (6) month cycle. All consultant reports are due at the Board office within thirty (30) days of the consultant's visit to the pharmacy. The consultant shall be hired at Respondent's expense.

8. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

9. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

10. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

B. Upon the expiration of said discipline, Respondent's license as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline Respondent.

C. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

D. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

E. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

F. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement

Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

**RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,**

**_____REQUESTS**

**_____DOES NOT REQUEST**

**THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE AS A PHARMACY.**

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's permit and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's permit. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's permit, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT

REHOBOTH PHARMACY, LLC

By: _____

As Authorized Agent for
REHOBOTH PHARMACY, LLC

Printed: _____

Date: 8/2/18

PETITIONER

MISSOURI BOARD OF PHARMACY

By: _____

Kimberly Grinston
Executive Director

Date: 8-7-18

NEWMAN, COMLEY & RUTH P.C.

By: _____

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